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(71)(72) Applicant and Inventor: ROSENGREEN, Lea, T. [FI/US]; 23021 Giant Fir Place, Sun City, CA 92587 (US).

(74) Agents: McCLAIN, James, W. et al.; Brown, Martin, Haller & McClain, 1660 Union Street, San Diego, CA 92101-2926 (US).

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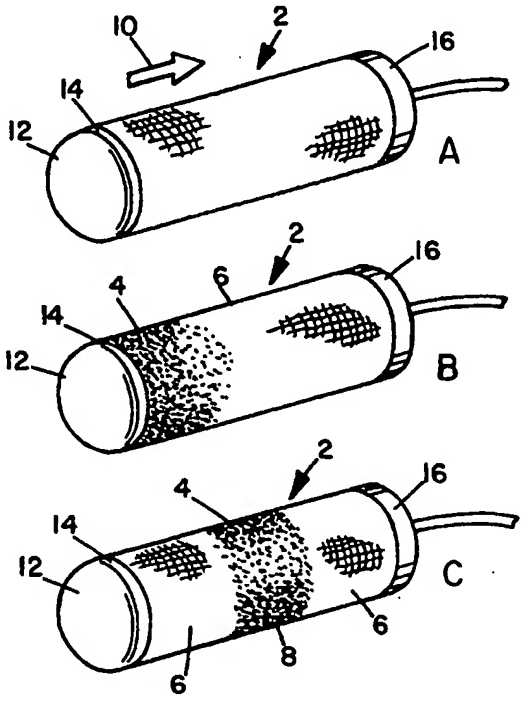
(54) Title: WEARABLE AMNIOTIC FLUID DETECTION DEVICE

(57) Abstract

An absorbent pad or tampon is defined which permits a pregnant woman herself to determine with a reasonable degree of accuracy whether or not she has expelled amniotic fluid. The absorbent pad or tampon intended to be worn by the pregnant woman contains a detector or indicator chemical which produces a visual change (usually a color change) in the pad upon contact with amniotic fluid which is leaked or otherwise discharged from the amnion. The woman wearing the device can observe the visual change and know with a reasonable degree of certainty whether or not the discharged fluid was amniotic fluid, and thus know whether to contact her medical advisor. Preferably the chemical indicator is a dye, and more preferably nitrazine or a related chemical. Further, from this invention, permitting immediate detection of discharged amniotic fluid by the woman herself, a physician can determine the imminence of a pregnant woman's delivery of her infant or detect the potential for there to be a fetal abnormality or other dysfunctional pregnancy.



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WEARABLE AMNIOTIC FLUID DETECTION DEVICE

BACKGROUND OF THE INVENTION

Field of the Invention:

The invention herein relates to identification of discharge of amniotic fluid by a pregnant woman. More particularly it related to devices for differentiation of amniotic fluid discharged by a pregnant woman from other bodily fluids which may be discharged by the woman.

Description of the Prior Art:

When a woman is pregnant, the growing fetus within her uterus is surrounded by the amnion, a liquid-tight membrane. Within the amnion and also surrounding the fetus is amniotic fluid. The amniotic fluid serves multiple functions, including cushioning the fetus from physical shock; see Sandler (ed.), AMNIOTIC FLUID AND ITS CLINICAL SIGNIFICANCE , (Marcel Dekker, Inc.: 1981). In a normal pregnancy, shortly before the woman goes into labor to deliver the infant the amnion ruptures, and the bulk of the amniotic fluid is expelled by the woman through her vagina. This occurrence of having "her water break" is usually one of the first indications that delivery is imminent.

In many cases, rupture of the amnion and discharge of the amniotic fluid is a very distinct and evident event with a relatively large amount of amniotic fluid being expelled, so that the woman knows immediately that she should contact her physician and prepare for delivery. In other cases, however, there may only be a small amount of amniotic fluid discharged, perhaps leakage as a precursor to the full rupture of the amnion and discharge of the remainder of the amniotic fluid, or because the amnion contained only a small amount of fluid in total. Thus it is not uncommon for a woman who is nearing her due date for delivery to detect the presence of liquid in her perineal area and be unsure whether the liquid is amniotic fluid or another bodily fluid (e.g., urine or perspiration).

In many cases, the woman's detection of liquid in her pudendal area turns out to be a "false alarm" with respect to the impending birth of her infant. For instance, women in advanced state of pregnancy tend to leak small amounts of urine through the urethra due to the pressure of the fetus and uterus against the bladder. However, because the woman has no convenient way to differentiate between small amounts of amniotic fluid and small amounts of other fluids such as urine, she must visit the

physician or hospital, only to be sent home again when the medical personnel determine that the liquid is not amniotic fluid. It is not uncommon for a woman, particularly a first time mother, to make repeated visits to the doctor or hospital for numerous such "false alarms," thus unduly burdening the medical personnel, as well as inconveniencing the woman and those family members who may have to accompany her to the doctor's office or hospital.

Further, the appearance of amniotic fluid discharged by a woman during an earlier stage of her pregnancy, well before her anticipated due date for delivery, can be a sign of fetal abnormality or some other problem with the progress of the pregnancy. It is imperative at such time that the woman consult with her physician to identify whether the expulsion of amniotic fluid is benign, or whether it signifies some significant difficulty with the pregnancy. However, because a woman will know that her delivery date is still some time off, and not being able to identify the discharged liquid, she may disregard the appearance and assume that the liquid is merely urine leakage or perspiration. By not being able readily to identify the appearance of amniotic fluid, she may thereby miss an important indicator of potential medical problems and not be aware that she should consult with her physician.

Currently, to determine whether or not a discharged liquid is or is not amniotic fluid, the woman must be examined by medical personnel at her doctor's office, a hospital emergency room or a maternity clinic. For many years, obstetrical physicians and nursing personnel have used "nitrazine paper" as the initial screening test to determine whether liquid expelled by a pregnant woman is amniotic fluid. Nitrazine paper contains an indicator dye which, when a sample of a woman's discharged bodily fluid is placed on the dye impregnated paper, turns to a color which is indicative of the pH of the fluid sample. Since amniotic fluid generally has a pH which can be differentiated from the pHs of urine, perspiration and other bodily fluids, an initial identification of the liquid as amniotic fluid can be made. In practice, this is normally confirmed by use of more comprehensive tests, such as ferning, to unequivocally avoid confusion of amniotic fluid with identification of urine, perspiration or other bodily fluid. Of course, all of these tests can presently be made only at medical facilities.

SUMMARY OF THE INVENTION

There has heretofore been no way for a pregnant woman herself to determine with a reasonable degree of accuracy whether or not she has expelled amniotic fluid. As noted, in the past the woman would merely detect the presence of fluid in her

pudendal area and thereupon be required to visit the physician or hospital to have the nature of the fluid analyzed by medical personnel. By use of the device of the present invention, however, a pregnant woman can determine promptly and reliably whether or not discharged fluid is or is not amniotic fluid, so that she can decide immediately whether or not consultation with her physician or with other medical personnel is needed. Thus, by use of the device of this invention the woman can essentially eliminate false alarms and determine the appropriate events for seeing the physician or going to the hospital, rather than contacting her physician or hospital indiscriminately anytime she senses that she has expelled liquid.

In a typical form, the device of the present invention is an absorbent pad or tampon intended to be worn by the pregnant woman within or at the exterior of her vagina, such that if amniotic fluid is leaked or otherwise discharged from the amnion it will be absorbed into the pad or tampon (or any similar "mat-like" material.) Within the pad or tampon is a detector chemical which, when contacted by the absorbed fluid, creates a readily perceivable change in the pad or tampon which is distinctive for identification of amniotic fluid. Most commonly the change will be something visual, usually a distinction color change or the appearance of color where color had not previously been perceivable. Thus a woman wearing such a pad or tampon, upon sensing her discharge of fluid, can visually inspect the pad or tampon, see if the distinctive change (such as of color) has occurred, and know with a reasonable degree of certainty whether or not the discharged fluid was amniotic fluid. Preferably such a color or other change would also be such that would help identify discharged fluids other than amniotic fluid, such as urine, so that the woman would have additional confirmation that the fluid was not amniotic fluid.

Thus, in its broadest embodiment, the invention herein is a wearable device for the detection of amniotic fluid, which comprises an absorbent mat configured to be worn within or at the exterior of the vagina of a pregnant woman, the mat containing an indicator responsive to the presence of amniotic fluid absorbed from the woman by the mat, in sufficient quantity to produce a first visual change in the appearance of the mat when amniotic fluid from the woman contacts the contained indicator within the mat, the visual change produced by the indicator upon contact with amniotic fluid being different from a second visual change produced by the indicator upon contact with any other bodily fluid from the woman.

Preferably the chemical indicator is a dye, and more preferably nitrazine or a related chemical.

In another embodiment of the invention, it involves a method for detection of rupture of the amnion of a pregnant woman which comprises providing a wearable device comprising an absorbent mat configured to be worn within or at the exterior of the vagina of the pregnant woman, the mat containing an indicator responsive to the presence of amniotic fluid absorbed from the woman by the mat, in sufficient quantity to produce a first visual change in the appearance of the mat when amniotic fluid from the woman contacts the contained indicator within the mat, the visual change produced by the indicator upon contact with amniotic fluid being different from a second visual change produced by the indicator upon contact with any other bodily fluid from the woman; having the device worn by the pregnant woman; and detecting by observing that the first visual change has occurred that amniotic fluid has been expelled by the pregnant woman into contact with the device, the expulsion of amniotic fluid identifying rupture of the pregnant woman's amnion.

Further, from such detection method a physician can determine the imminence of a pregnant's woman's delivery of his infant or detect the potential for there to be a fetal abnormality or other dysfunctional pregnancy.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 includes three perspective views (A, B and C) of a typical device of the present invention in the form of a vaginal tampon, illustrating schematically two examples of a visual change indicating that the tampon has absorbed amniotic fluid.

Figure 2 includes two perspective views (A and B) of a device of the present invention in the form of a perineal pad, also illustrating schematically another example of a visual change indicating that the pad has absorbed amniotic fluid.

Figure 3 includes two partial side elevation views (A and B) of two typical examples of a perineal pad of the present invention.

DETAILED DESCRIPTION AND PREFERRED EMBODIMENTS

The present invention is a device which enables a pregnant woman to determine immediately and by her own visual inspection whether or not a bodily fluid which she has discharged is or is not amniotic fluid. Preferably the device will also permit her to identify both amniotic fluid and other bodily fluid such as urine or perspiration which may be discharged. Essentially, the device is an absorbent mat which is configured for the woman to wear either internally in the vagina, such as in the form of a tampon, or externally, such as in the form of a pad covering her perineal area and in particular, the

external end of the vagina. The mat, which is absorbent for expelled bodily fluids, is preloaded with an effective quantity of an indicator, commonly a dye, which when contacted with amniotic fluid reacts to produce a distinct and readily visible change in the appearance of the mat. Most commonly, this visible change will be a change in color of that portion of the mat where the bodily fluid has been absorbed and contacted the indicator. The color change may be from one color to another, or from an uncolored appearance, i.e., the only color being that of the mat itself or a porous covering, to a distinct colored appearance of another color. Upon sensing the expulsion of liquid from her body, the woman can then promptly and easily remove the pad or tampon containing the absorbent mat and visually inspect it to detect the change in appearance, usually being the change in color. Since the color change by reaction of the amniotic fluid and the indicator will be distinctive, the woman can readily determine whether or not the fluid expelled was amniotic fluid and thus know whether to consult with her obstetrical care provider.

Examples of the visual changes upon absorption of amniotic fluid (or other fluids) are shown in Figure 1 and 2. Figure 1 shows in View A a tampon 2 (before use) made of a matted, absorbent material, which has incorporated into it an indicator which is clear, of a color substantially the same as the overall color of the tampon 2, or of a color which is distinctively different from the color which will appear upon contact with amniotic fluid. The pregnant woman inserts the tampon 2 and wears it in a normal manner, for time periods to be described below. Tampons may require changing at appropriate intervals. If amniotic fluid is discharged from her amnion, it will have to pass through the tampon 2 as it flows through her vagina, and thus will contact the indicator incorporated into the tampon mat. As the two contact, the indicator will change color according to the pH of the amniotic fluid, thus turning the indicator color to visible, distinctive color 4, as indicated in Views B and C. The woman, having sensed the flow of liquid, will then remove the tampon and visually observe the presence of the identifying color 4, thus confirming to her that she has discharged some quantity of amniotic fluid, and should contact her physician. If the color of the tampon is not the identifying color 4, the woman will know that the fluid absorbed by the tampon 2 is not amniotic fluid.

Views B and C in Figure 1 illustrate two different versions of the tampon 2. In View B the entire absorbent mat 6 is impregnated with the indicator. The discharged fluid, which flows in the direction of the arrow 10, thus encounters interior end 12 of the tampon first, so that the bulk of the discharged fluid is absorbed starting adjacent to end

12 and tapering off over the length of the tampon 2 as the fluid is progressively absorbed, as indicated by the location of color 4 shown in View B. In contrast, in View C, the indicator is impregnated into the mat 6 over only one or more discrete volumes 8, so that no color indication 4 appears until the discharged fluid passes through a portion of the mat 6 and reaches the impregnated volume 8, as indicated by the color 4 in View C. The configuration of View C will require less indicator, but will be less sensitive, especially to minor discharges, since much or perhaps all of the discharged fluid may be absorbed by the upstream unimpregnated portion of the tampon 2 and therefore not reach the impregnated volume 8 to activate the indicator. Generally the configuration of View B will be preferred, both for the better sensitivity and also for ease of manufacture.

Figure 1 also illustrates two optional features of the tampon 2. Preferably at internal end 12 there is a non-reactive cap or zone 14 which is unaffected by liquid contact. This is to allow insertion of the tampon into the vagina without causing activation of the indicator, or otherwise cause discoloration of the mat 6, by residual moisture or bodily fluids which may be initially in the vagina or adhering to the vaginal walls. The cap or zone 12 can absorb those residual liquids or fluids, thus removing them from possible competition for detection with subsequently discharged amniotic fluid, especially small quantity discharges.

At the opposite end of the tampon 12, there may be a substantially fluid impermeable cap or zone 16, to prevent excess discharged fluid from flowing through the tampon 2 and appearing at the vaginal exit, where it could soil or mark the woman's undergarment or other clothing.

Figure 2 is similar to Figure 1, except that the device is in the form of a perineal- or menstrual-type pad 18 as shown in View A. The indicator in this embodiment is incorporated throughout the mat 6 comprising the pad 18. Since the pad is worn externally and extends along the perineal area, it may be contacted by amniotic fluid, urine or perspiration discharged respectively from the vagina, urethra or sweat glands. Thus when the woman discharges some fluid, the resulting color of the indicator will indicate which fluid it is. While with very minor discharges, the location of the appearance of the color 4 may also give some indication of the identity of the discharged fluid, the tendency of the fluid to flow within the mat 6 usually makes location of little value in identifying the discharged fluid. As with the tampon 2, sensing of liquid discharge will alert the woman to remove the pad 18 for visual examination, and observation of the color of the indicator will indicate to the woman whether she has

discharged amniotic fluid and needs to contact her physician. Usually the appearance of the pad 18, particularly with a small discharge, will be substantially as shown in View B, with the greatest concentration of color 4 being at the contact point of the fluid being discharged from the vagina or urethra, with the concentration of color lessening as the fluid disperses outwardly from that point.

It is possible, but less desirable, to impregnate with indicator only that portion of pad 18 generally adjacent to the vaginal and urethral exits, in a manner analogous to the partial impregnation of the tampon 2 illustrated in View C of Figure 1. However, as in that case, partial impregnation of the pad 18 reduces sensitivity (particularly if the pad 18 shifts while being worn) and is more difficult to manufacture.

(While other forms of visual changes, such as the appearance of crystallized or gelled solid materials formed by the reaction of amniotic fluid and the indicator chemical are possible, depending on the specific indicator chemical, color change is the most preferable change since it is usually the change most readily recognized by a woman. Color change will therefore be discussed herein as the exemplary form of the invention. It will be understood, however, that this use of color change as the example described is not intended to limit the application of the invention to only that embodiment. All other forms of visual indication of amniotic fluid discharge and absorption by the pad, tampon, etc. are also intended to be included herein, although not discussed expressly to the same extent as the discussion of color change.)

In further reference to Figures 2 and 3, preferred aspects of the pad embodiment may be seen. The pad 18 is generally configured as a perineal pad, similar in configuration to common catamenial or menstrual pads. The pad 18 may be in a stand-alone form in which it is worn using a common support belt, or it may be in the form of an adhesive-backed pad which can be inserted in a woman's normal undergarment in the form of a crotch portion liner, or it may be an entire unitary panty-type garment with at least the crotch portion being made of the absorbent mat material 6. In View A of Figure 3, the pad 18 is shown as having an optional porous cover 20 on the surface of the mat 6 which contacts the wearer's perineal skin. This cover 20 will be of a material which provides comfortable contact with the skin, and will be made of porous materials equivalent to those used for the body contact side of conventional menstrual pads. The one property which may be difference from menstrual pad covers, however, is that the cover 20 must be transparent, of a suitably light color, or translucent, so that the color 4 of the activated indicator can be observed.

The pad 18 in View A may also have a fluid impermeable sheet 22 on the opposite, non-body-contact side of the mat 6, to prevent the escape of excess discharged fluid from the pad, in an analogous manner to tampon cap or zone 16.

The embodiment illustrated in View B of Figure 3 is of a thin pad 18, in the form of a "panty liner." There will preferably be a top cover 20', essentially equivalent to cover 20 in View A, having the same light color, transparency or translucency, but not necessarily being of the same material. On the opposite side there will preferably be a fluid impermeable layer 24, or the garment to which it will be attached may be of non-absorbent material. Finally, there will be an adhesive layer 26 to permit adhesion of the pad 18 to the inside of the crotch portion of the wearer's panty, pantyhose or equivalent undergarment (not shown). The adhesive in layer 26 will normally have sufficient adhesive strength to adhere well to the undergarment regardless of the wearer's movements, but to be removable from the undergarment with modest effort and no damage to the undergarment.

It will be recognized that a thin pad or the equivalent of a "light days" tampon will normally be all that is required. "False alarms" normally occur only when a woman experiences a minor discharge of fluid, which the pad or tampon would detect. When a woman's amnion fully ruptures, there is usually a significant volume of discharged amniotic fluid, which is quite unmistakable. While such would usually overwhelm a thin pad or light tampon, in such case the woman would not need the appearance of the indicator color 4 to assure her that her "water had broken" and that she should proceed to the doctor or the hospital for imminent delivery.

Whether the perineal pad or tampon configuration will be preferred will depend on the choice of the woman and her doctor. The externally worn pad, which covers the entire perineal area, will absorb and detect not only amniotic fluid expelled through the vagina, but also urine expelled through the urethra and perspiration expelled through the sweat glands. Thus, identification of particular fluids may be made readily and unequivocally by the resultant color of the indicator. On the other hand, the tampon configuration, being inserted into and retained in the vagina, is likely to detect only amniotic fluid and thus not be activated by the other discharged fluids such as urine or perspiration. Most women have a personal preference toward pads or tampons, usually depending on the product they normally use for menstrual periods, and will in most cases wish to continue with the same type of product for amniotic fluid detection. However, the woman's physician may consider it advisable for the present device to be

used only in the form of the external pad, rather than having a tampon within the vagina during the course of the pregnancy, particularly late in pregnancy.

Amniotic fluid can be readily differentiated from urine or perspiration by the pH of the respective liquids. Typically, amniotic fluid will have a pH of about 7.0-7.3, decreasing slightly as pregnancy advances; See Sandler, *supra*, p. 20. In contrast, typical pH for a woman's urine is approximately 5.8 and is approximately the same for perspiration; see Diem et al. (eds.), SCIENTIFIC TABLES (7th edn.; Geigy Pharm.: 1970), pp. 662 and 679.

The preferred detector for differentiating these fluids will be the same nitrazine detector as is currently used in the nitrazine papers. This material is described extensively in the literature as a dye. It may also in some cases be referred to by the common name phenapthazine, or by the common names "nitrazine yellow" or "nitrazol," although it is possible that such names might also be applied to compounds or compositions which are closely related to but not exactly the same as nitrazine. Further, nitrazine or the "nitrazine-equivalent" materials are believed to include the dye compound 2,4-dinitroaniline – 1-naphthol-3,6-disulfonic acid or the related sodium salt 3',6-disodium 2,4-dinitrobenzene-(1-azo-2')-naphthol-1'-disulphonate; see THE COLOUR INDEX, vol. 5, p. 4073, compound No. 14890 (Rev. 3rd edn.: 1976), and vol. 4, p. 5638 (3rd edn., 1971), both published by The Society of Dyers and Colourists; Németh, CHEMICAL TABLES, p. 383 (John Wiley & Sons; 1975); and Janko, U.S. Patent No. 4,357,945 (1982). Nitrazine is known to have a color change pH range of about 4.5-8.0, in which the color changes from a yellow through green to dark blue as the alkalinity increases. Urine and sweat, being more acidic, generally fall into the green color range while amniotic fluid falls into the blue color range. The color differences are sufficiently distinct that the ordinary lay woman can readily identify the respective color and thus make a reliable identification of the nature of the discharged fluid.

It will be understood that the use of nitrazine or other indicator chemicals in the pads, tampons, etc. herein is only an initial screening test which permits the woman to make an quick determination that the fluid that she has expelled is likely to be amniotic fluid. As with the nitrazine papers used in the past by physicians and other medical personnel, the test is strongly indicative but not entirely conclusive. More precise tests, commonly such as the ferning test, will thereafter be used by the medical personnel to confirm the presence of the amniotic fluid. The present invention is therefore not intended to be an absolute diagnostic device, but rather is intended to provide the pregnant woman with a rapid and readily identified indication to her from which she can

to determine whether or not she needs to contact her physician or the hospital for further confirming tests. Thus the pregnant woman can to make an appropriate judgment as to the need for physician contact and avoid a "false alarm." It will of course also be understood that should the woman have any doubt about the identification or significance of any specific appearance or visual change caused by the indicator, she should of course definitely contact the physician or other medical personnel promptly.

The amount of indicator to be present in the mat forming the pad or tampon will be determined by the sensitivity of the particular indicator chosen and by the size of the pad or tampon. These quantities may be readily determined by those skilled in the art simply by, in the case of nitrazine, converting the quantity of nitrazine compound in a typical nitrazine paper to the quantity size for the intended effective area of the pad or tampon, by providing a quantity such that the respective concentrations are approximately the same. It is not necessary that the concentration of the indicator be uniform across the pad or tampon, but there should be a sufficient area of effective concentration that expelled fluids cannot readily bypass the indicator and thus go undetected.

While nitrazine will be the preferred material, it will be recognized that there are other types of dyes and similar chemical indicators which function over an equivalent pH range or other range of change, and which have sufficient visible change, usually in the form of distinct color changes, to allow the woman to make the appropriate initial differentiation between absorbed amniotic fluid and absorbed urine or perspiration. It is preferred that an indicator chosen have a gradual color change over the appropriate pH range, rather than having an abrupt color change over a very narrow pH range. This is because the pH's of the various bodily fluids of interest do vary over known ranges as indicated above, such that a sharp cutoff point for color change will not necessarily adequately differentiate the different materials. A gradual range of color change, as with nitrazine, will allow for better differentiation of the different bodily fluids, notwithstanding that the actual pH of the fluids for any particular woman and at different stages of her pregnancy may vary slightly within their known ranges. Thus, while nitrazine or the nitrazine analogs are preferred, it will be understood that other indicators of similar functionality for amniotic fluid, whether heretofore known or subsequently discovered or developed, are considered to be within the scope of this invention, as long as they meet the criteria set forth herein.

Similarly, many absorbent materials suitable for use in the devices of this invention are known. Principal among these will be the types of fibrous or felted materials commonly used for catamenial or menstrual pads and tampons. Other materials which may be suitable include materials which are used for disposable diapers for infants. These are all well known and widely described in patents and medical literature, and need not be detailed here. Those skilled in the art will be readily able to select appropriate materials for any type of pad, tampon or other configuration of the present devices.

It will of course be understood that all indicators, mat materials, covers, adhesives and any other components of the devices must be harmless and inert to the woman, especially to her skin and urinogenital organs, and also to the fetus.

It is contemplated that the devices of the present invention will be available either through a woman's physician or hospital, or over the counter at pharmacies, drugstores and similar establishments, in the same manner that pregnancy indicator kits for home use are currently available. Since the present invention serves merely to provide a visual indication that amniotic fluid may be present, and does not affect the woman's body or the fetus in any manner, it is anticipated that the device will not require a physician's prescription to obtain. While physicians may recommend to some or all of their patients that they use these devices, particularly as their anticipated delivery dates approach, it is also anticipated that a pregnant woman may herself choose to use these devices not only toward the end of her pregnancy, but also during earlier stages, such that she can be assured that amniotic fluid is not expelled during such earlier period of the pregnancy because of some physical or medical problem.

The devices of the present invention are considered to be "one time use" pads or tampons, since once the indicator has been activated, the device cannot be reused.

In its most common anticipated use, pads or tampons of the present invention will be worn by a pregnant woman from time to time during the last days of her pregnancy, as her delivery date approaches. Normally the woman will not wear the devices continually, but rather use them only when she senses that she has or will begin some degree of fluid discharge. The actual amount of time of using the pads or tampons of the present invention will be determined by the woman and her physician. If for instance, a woman has a prior history of having delivered previous children before the scheduled due date, the physician will likely recommend that the woman begin using the present devices at an earlier date, anticipating that her amnion will rupture well before her due date, thus indicating that her delivery is imminent, notwithstanding that

her nominal due date is still some days off. Also, in anticipated usage, it is likely that physicians and other hospital personnel will recommend use of a device of the present type to any woman who presents herself to the physician or medical personnel with a "false alarm" as her delivery date approaches, in order to avoid further false alarms and be assured that when the actual rupture of the amnion occurs, it will be unequivocally detected.

Use of the present devices can also serve to aid the physician in determining the state of a woman's pregnancy and determining whether or not the date predicted for her delivery is accurate. When a woman contacts her physician after seeing the anticipated change in the pad or tampon that she is wearing, the physician can then conduct sufficient other tests to determine whether or not the amniotic fluid detected was merely minor leakage such that the amnion has not fully ruptured but has merely developed minor benign leakage, or whether the delivery is imminent.

It is further contemplated that the device of the present invention may be used at any stage of the a woman's pregnancy to aid in detecting potential problems with the pregnancy or fetal abnormalities. If such is suspected, or if the woman has a prior history of such events, her physician may recommend that she use the present devices at the appropriate time in her pregnancy, and perhaps even throughout much of the pregnancy. Thus the discharge of amniotic fluid at any time will be detected and the physician can conduct further diagnostic tests as appropriate.

It will be evident from the above that there are numerous embodiments of this invention which, although not expressly described above, are clearly within the scope and spirit of the invention. The above description is therefore intended to be exemplary only, and the full scope of the invention is to be determined solely by the appended claims.

I CLAIM:

CLAIMS

1. A wearable device for the detection of amniotic fluid, which comprises an absorbent mat configured to be worn within or at the exterior of the vagina of a pregnant woman, said mat containing an indicator responsive to the presence of amniotic fluid absorbed from said woman by said mat, in sufficient quantity to produce a first visual change in the appearance of said mat when amniotic fluid from said woman contacts said contained indicator within said mat, said visual change produced by said indicator upon contact with amniotic fluid being different from a second visual change produced by said indicator upon contact with any other bodily fluid from said woman.

2. A device as in Claim 1 wherein said device is in the form of a tampon to be worn within the vagina.

3. A device as in Claim 1 wherein said device is in the form of a pad to be worn covering the external end of the vagina.

4. A device as in Claim 1 wherein said first visual change comprises a change in the color of at least a portion of said mat.

5. A device as in Claim 1 wherein said first visual change comprises the development of color in at least a portion of said mat which previously had been devoid of color.

6. A device as in Claim 1 wherein said indicator comprises a chemical which changes color upon contact with amniotic fluid, said color change comprising said first visual change.

7. A device as in Claim 6 wherein said chemical comprises a dye.

8. A device as in Claim 7 wherein said dye comprises nitrazine.

9. A device as in Claim 7 wherein said dye comprises 2,4-dintiroaniline - 1-naphthol-3,6-disulfonic acid.

10. A device as in Claim 7 wherein said dye comprises 3',6-disodium 2,4-dinitrobenzene-(1-azo-2')-naphthol-1'-disulphonate.

11. A method for detection of rupture of the amnion of a pregnant woman which comprises:

providing a wearable device comprising an absorbent mat configured to be worn within or at the exterior of the vagina of said pregnant woman, said mat containing an indicator responsive to the presence of amniotic fluid absorbed from said woman by said mat, in sufficient quantity to produce a first visual change in the appearance of said mat when amniotic fluid from said woman contacts said contained indicator within said mat, said visual change produced by said indicator upon contact with amniotic fluid being different from a second visual change produced by said indicator upon contact with any other bodily fluid from said woman;

having said device worn by said pregnant woman; and

detecting by observing that said first visual change has occurred that amniotic fluid has been expelled by said pregnant woman into contact with said device, said expulsion of amniotic fluid identifying rupture of said pregnant woman's amnion.

12. A method as in Claim 11 wherein said device is in the form of a tampon and said wearing by said woman comprises said tampon being disposed with said woman's vagina.

13. A method as in Claim 11 wherein said device is in the form of a pad and said wearing by said woman comprises said pad being disposed covering the external end of said woman's vagina.

14. A method as in Claim 11 wherein said first visual change comprises a change in the color of at least a portion of said mat.

15. A method as in Claim 11 wherein said first visual change comprises the development of color in at least a portion of said mat which previously had been devoid of color.

16. A method as in Claim 11 wherein said indicator comprises a chemical which changes color upon contact with amniotic fluid, said color change comprising said first visual change.

17. A method as in Claim 16 wherein said chemical comprises a dye.

18. A method as in Claim 17 wherein said dye comprises nitrazine.

19. A method as in Claim 17 wherein said dye comprises 2,4-dintiroaniline – 1-naphthol-3,6-disulfonic acid.

20. A method as in Claim 17 wherein said dye comprises 3',6-disodium 2,4-dinitrobenzene-(1-azo-2')-naphthol-1'-disulphonate.

21. A method as in Claim 11 further comprising the step of correlating the occurrence of said expulsion of amniotic fluid with the then-current status of said woman's pregnancy, and thereby determining the imminence of said woman's delivery of her child.

22. A method as in Claim 11 further comprising the step of correlating the occurrence of said expulsion of amniotic fluid with the then-current status of said woman's pregnancy, and thereby diagnosing the potential for the presence of a fetal abnormality or a dysfunctional pregnancy.

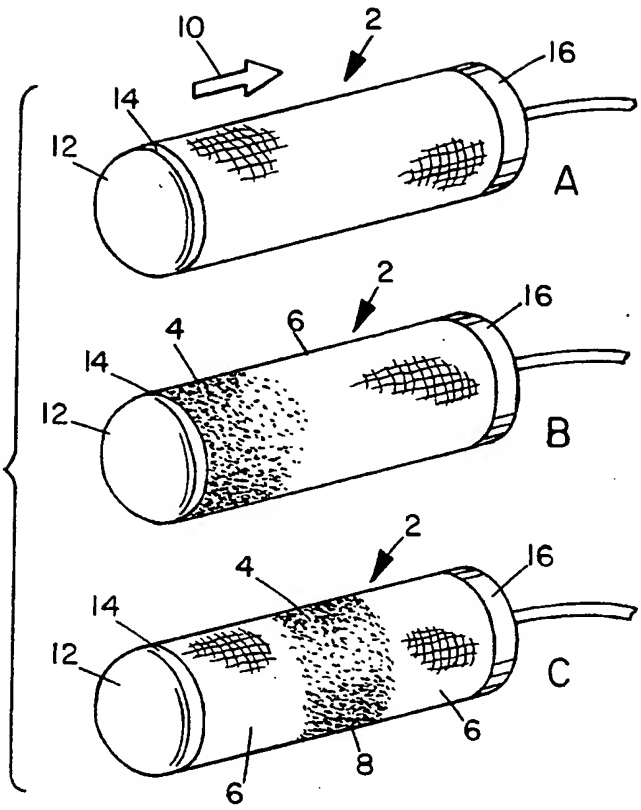

FIG. 1

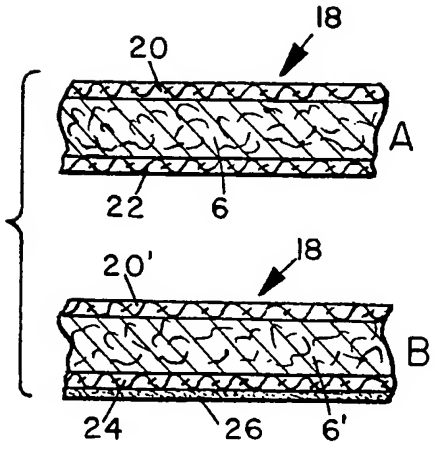

FIG. 3

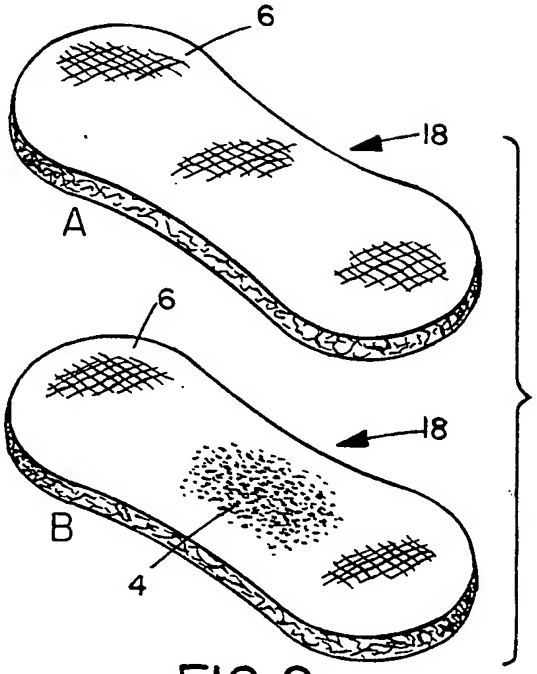

FIG. 2

INTERNATIONAL SEARCH REPORT

Interr al Application No
PCT/US 98/11982

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01N31/22 G01N33/84 G01N33/52 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G01N A61B A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category ³	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Week 9325 Derwent Publications Ltd., London, GB; AN 93-199764 XP002079894 YAZAKI KATSUMI: "Pad for detecting rupture of bag of amniotic fluid - comprises pH indicator sheet impregnated with bromo thymol blue" & JP 05 123324 A (HAKUJUJI KK) , 21 May 1993	1-7, 11-17, 21,22
Y	see abstract --- US 5 425 377 A (CAILLOUETTE JAMES C) 20 June 1995 see column 2, line 64 - column 3, line 17 --- -/--	8-10, 18-20 8-10, 18-20

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

³ Special categories of cited documents :

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 October 1998	19/10/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hart-Davis, J

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 357 945 A (JANKO ALBERT B) 9 November 1982 cited in the application see column 2, line 18 - line 46	8-10, 18-20
A	US 5 597 700 A (KONSTANTINOV ALEXANDER ET AL) 28 January 1997 see column 1, line 19 - column 3, line 29	1-22
A	US 4 287 153 A (TOWSEND MARVIN S) 1 September 1981 see column 1 - column 2	1-22

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INTERNATIONAL SEARCH REPORT

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